

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Andrew Cook *et al.*
Title: METHOD DETECTING RHEUMATOID ARTHRITIS EMPLOYING
THE CB10 PEPTIDE FO MAMMALIAN TYPE II COLLAGEN AS
AN ANTIGEN
Prior Appl. No.: 09/623,497, filed 11/20/2000
Appl. No.: Unassigned
Filing Date: February 9, 2004

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Mail Stop PATENT APPLICATION
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Alexandria, Virginia 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. In accordance with 37 CFR §1.98(d)(1), no copy of the listed documents are being provided because they were either cited by applicants, the USPTO, or an examining authority in a corresponding international application.

The USPTO has waived the requirement under 37 CFR 1.98(a)(2)(i) to submit copies of U.S. patents and U.S. patent application publications when citing and submitting an Information Disclosure Statements in a patent application filed after June 30, 2003 and in an international application that has entered the national stage under 37 USC §371 after June 30, 2003. Accordingly, copies of these types of documents are not being supplied in connection with this application. Reference is being made to Pre-OG Notice from Office of Patent Legal Administration dated July 25, 2003, *Information Disclosure Statements May Be Filed Without Copies of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003.*

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relevant by the examiner is attached.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

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Respectfully submitted,

Date February 9, 2004

By 

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| | | | | Application Number | Unassigned |
| | | | | Filing Date | 02/09/2004 |
| | | | | First Named Inventor | Andrew Cook et al. |
| | | | | Group Art Unit | Unassigned |
| | | | | Examiner Name | Unassigned |
| | | | | Attorney Docket Number | 017227-0197 |
| Sheet | 1 | of | 5 | | |

| U.S. PATENT DOCUMENTS | | | | | | |
|-----------------------|-----------------------|----------------------|-----------------------------------|---|---|---|
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| | B1 | JP | 62-12800 | A | JAPAN | 01/21/1987 | | |
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| | C1 | Andersson, M. A., et al., "Analysis of Type II Collagen Reactive T Cells in the Mouse" Scand. J. Immunol, Vol. 33, pp. 505-510 (1991) | | |
| | C2 | Miyahara, H., et al., "Identification and Characterization of a Major Tolerogenic T-cell Epitope of Type II Collagen that Suppresses Arthritis in B10.RIII Mice", Immunology, Vol. 86, pp. 110-115 (1995) | | |
| | C3 | Nabozny, G.H., et al., "Identification of a Cyanogen Bromide Fragment of Porcine Type II Collagen Capable of Modulating Collagen Arthritis in B10.RIII (H2 ⁿ) Mice ¹ ", Autoimmunity Vol 20, pp. 39-49 | | |
| | C4 | Kerwar, S.S., et al., "Type II Collagen Induced Arthritis in Rats: Clinical and Immunological Studies", Int. J. Tiss. Reac. Vol. VII(6), pp. 409-429 | | |
| | C5 | Rowley, M.J., et al., "Epitope Specificity of Antibodies to Type II Collagen in Rheumatoid Arthritis and Systemic Lupus Erythematosus", Rheumatology International, Vol. 12(2), pp. 65-69. | | |
| | C6 | Boissier, M.C., et al., "Role De La Conformation Du Collagene Dans L'Immunité Anti-Collagene De Type II Au Cours De La Polyarthrite Rhumatoïde", Revue du Rhumatisme, Vol. 58(1), pp. 19-24 (1991) | | |
| | C7 | | | |
| | C8 | | | |

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| OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i> | | | | | | | |
| | | Bornstein, P. and Sage, H. (1980). Structurally distinct collagen Types. Ann. Rev. Biochem. 49:957-1003. | | | | | |
| | | Brodsky, B. and Shah, N.K. (1995). The triple-helix motif in proteins FASEB J. 9:1537-1546 | | | | | |
| | | Buckee, C., Morgan, K., Ayad, S., Collins, I., Clague, R.B., Holt, P.J.L. (1990). Diversity of antibodies to type II collagen in patients with rheumatoid arthritis: detection by binding to -chains and to cyanogen bromide peptides. Brit. J. Rheumatol. 29:254-258 | | | | | |
| | | Charriere, G., Hartmann, D.J., Vignon, E., Ronziere, M-C., Herbage D., Ville, G. (1988). Antibodies to types I, II, IX, and XI collagen in the serum of patients with rheumatic diseases. Arthritis Rheum. 31:325-332. | | | | | |
| | | Choi, E.K.K., Gatenby, P.A., McGill, N.W., Bateman, J.F., Cole, W.G., York, J.R. (1988). Autoantibodies to type II collagen: occurrence in rheumatoid arthritis, other arthritides, autoimmune connective diseases, and chronic inflammatory syndromes. Ann. Rheum. Dis. 47:313-322. | | | | | |
| | | Clague, R.B., Shaw, M.J., Holt, P.J.L. (1980). Incidence of serum antibodies to native type I and type II collagen in patients with inflammatory arthritis. Ann. Rheum. Dis. 39:201-206. | | | | | |
| EXAMINER | DATE CONSIDERED | | | | | | |
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| | | FILING DATE 02/09/2004 | GROUP ART UNIT Unassigned |
| (Use several sheets if necessary) | | | |
| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) | | | |
| | | Collier, D.H., Kerwar, S.S., Garovoy, M.R., Fye, K.H., Stobo, J.D. (1984). Anticollagen antibodies and immune response gene products in rheumatoid arthritis. Arthritis Rheum, 27:1201-1209. | |
| | | Cook, A.D., Rowley, M.J., Stockman, A., Muirden, K.D., Mackay, I.R. (1994). Specificity of antibodies of type II collagen in early rheumatoid arthritis. J. Rheumatol. 21:1186-1191. | |
| | | Cook, A.D., Rowley, M.J., Mackay, I.R., Gough, A., Emery, P. (1996). Antibodies to type II collagen in early rheumatoid arthritis: correlation with disease progression. Arthritis Rheum 39:1720-1727. | |
| | | Courtenay, J.S., Dallman, M.J., Dayan, A.D., Martin, A., Mosedale, B. (1980). Immunization against heterologous type II collagen induces arthritis in mice. Nature 283:666-667. | |
| | | Fujii, K., Tsuji, M., Kitamura, A., Murota, K. (1992). The diagnostic significance of anti-type II collagen antibody assay in rheumatoid arthritis. Int. Orthop. 16:272-276. | |
| | | Gay, S., Gay R.E. and Miller, E.J. (1980). The collagens of the joint. Arthritis Rheum. 23:937-941. | |
| | | Gioud, M., Meghlaoui, A., Costa, O., Monier, J.C. (1982). Antibodies of native type I and II collagens detected by an enzyme linked immunosorbent assay (ELISA) in rheumatoid arthritis and systemic lupus erythematosus. Collagen Rel. Res. 2:557-564. | |
| | | Heinegard, D. and Paulsson, M. (1987). Methods Enzymol. 145:336-363. | |
| | | Hochberg, M.C. (1981). Adult and Juvenile rheumatoid arthritis: current epidemiologic concepts. Epidemiol. Rev. 3:27-44. | |
| | | Miller, E.J. (1985). The structure of fibril-forming collagens. Ann. N.Y. Acad. Sci. 460:1-13. | |
| | | Miller, E.J. and Lunde, L.G. (1973). Isolation and characterization of the cyanogen bromide peptides from the alpha-I(II) chain of bovine and human cartilage collagen. Biochem 12:3153-3159. | |
| | | Miller, E.J. and Rhodes, R.K. (1982). Preparation and characterization of the different types of collagen. Meth. Enzymol. 82:33-64. | |
| | | Morgan, K., Clague, R.B., Collins, I., Ayad, S., Phinn, S.D., Holt, P.J.L. (1987). Incidence of antibodies to native and denature cartilage collagens (types II, IX, and XI) and to type I collagen in rheumatoid arthritis. Ann. Rheum. Dis. 46:902-907. | |
| | | Morgan, K., Clague, R.B., Collins, I., Ayad, S., Phinn, S.D., Holt, P.J.L. (1989). A longitudinal study of anticollagen antibodies in patients with rheumatoid arthritis. Arthritis Rheum. 32:139-145. | |
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Pereira, R.S., Black, C.M., Duance, V.C., Jones, V.E., Jacoby, R.K., Welsh, K.I. (1985) Disappearing collagen antibodies in rheumatoid arthritis. *Lancet ii* :501-502.

Piez, K.A. (1976). Primary structure. In *Biochemistry of collagen*. Ramchandran, G.H. and Reddi, A.N. (eds). Plenum, New York, pp 1-44.

Piez, K.A. (1982). Structure and assembly of the native collagen fibril. *Connect Tissue Res.* 10:25-36.

Rosenberg, A.M., Hunt, D.W.C., Pretty, R.E. (1984). Antibodies to native and denatured type II collagen in children with rheumatic diseases. *J. Rheumatol.* 11:425-431.

Rowley, M.J., Gershwin, M.E., Mackay, I.R. (1988). Collagen antibodies in juvenile arthritis and adult rheumatoid arthritis: differences in levels and type-specificity. *J. Rheumatol.* 15:289-294.

Rowley, M.J., Mackay, I.R., Brand, C.A., Bateman, J.F., Chan, D. (1992). Epitope specificity of antibodies of type II collagen in rheumatoid arthritis and systemic lupus erythematosus. *Rheumatol. Int.* 12:65-69

Scott, P.G. and Veis, A. (1976) The cyanogen bromide peptides of bovine soluble and insoluble collagens. *Connect Tissue Res.* 4:107-116.

Stuart, J.M., Huffstutter, E.H., Townes, A.S., Kang, A.H. (1983). Incidence and specificity of antibodies to types I, II, III, IV and V collagen in rheumatoid arthritis and other rheumatic diseases as measured by 125 I-radioimmunoassay. *Arthritis Rheum.* 26:832-840.

Steffen, C., Timpl R. (1963). Antigenicity of collagen and its application in the serological investigation of rheumatoid arthritis sera. *Int. Arch. Allergy Appl. Immunol* 22:333-349.

Stockman, A., Rowley, M.J., Emery, P., Muirden, K.D. (1989). Activity of rheumatoid arthritis and levels of collagen antibodies: a prospective study. *Rheumatol. Int.* 8:239-243

Terato, K., Cremer, M.A., Hasty, K.A., Kang, A.H., Hasty, D.L., Townes, A.S. (1985). Physicochemical and immunological studies of the renatured alpha I(II) chains and isolated cyanogen bromide peptides of type II collagen. *Coll. Rel. Res.* 5:469-480.

Terato, K., Shimozuru, Y., Katayama, K., Takemitsu, Y., Yamashita, I., Miyatsu, M., Fujii, K., Sagara, M., Kobayashi, S., Goto, M., Nishioka, K., Miyatsaka, N., Nagai, Y. (1990). Specificity of antibodies of type II collagen in rheumatoid arthritis. *Arthritis Rheum* 33:1493-1500.

Trentham, D.E. Townes, A.S., Kang, A.H. (1977). Autoimmunity to type II collagen: an experimental model of arthritis. *J. Exp. Med.* 146:857-868.

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| | | Trentham, D.E. Kammer, G.M., McCune, W.J., David, J.R. (1981). Autoimmunity to collagen. A shared feature of psoriatic and rheumatoid arthritis. Arthritis Rheum. 24:1363-1369. | |
| | | | |
| | | Werkmeister, J.A., Ramshaw, J.A. M (1991). Multiple antigenic determinants on type III collagen. Biochem J. 274:895-898. | |
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